## DETAILED ACTION

### *Specification*

The disclosure is objected to because of the following informalities:

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicants are reminded that sequences appearing in the specification and/or drawings (e.g., see pages 7 and 12-16 of the specification) must be identified by a sequence identifier (SEQ ID NO:X) in accordance with 37 C.F.R. § 1.821(d). Applicant must provide appropriate amendments to the specification and/or drawings inserting the required sequence identifiers.

Appropriate correction is required.

### *Drawings*

The drawings are objected to because they fail to include the appropriate figure designation (e.g., Figure 1) and Figure 2 is missing. Corrected drawing sheets in compliance with 37 C.F.R. § 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 C.F.R. § 1.121(d). The objection to the drawings will not be held in abeyance.

***Information Disclosure Statement***

The information disclosure statement filed April 4, 2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each document listed that is not in the English language. The documents have been lined through and not considered.

The information disclosure statement filed May 26, 2005 has not been considered because it lists duplicate references from the information disclosure statement filed May 26, 2005.

***Claim Objections***

Claims 1-5 are objected to because of the following informalities: Claim 1 should recite SEQ ID NO:1 instead of sequence No. 1 (the same applies to SEQ ID NO:2).

Claims 4 should recite "A cell strain" instead of "A cell stain," and claim 5 should recite "The human IgM." In addition, claims 1 and 4 should recite that the antibody binds to activated cells instead of reactive to activated cells. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that cells FERM BP-8379 are required to practice the claimed invention. As such, the cells must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cells.

The cells disclosed in the specification do not appear to be produced from a repeatable process, and it is not apparent if the cells are both known and readily available to the public. It is noted that page 6 of the specification indicates that the cells

have been deposited; however, there is no indication in the specification as to public availability.

If the deposit was made under the terms of the Budapest Treaty, then a statement, affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, or someone empowered to make such a statement, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement.

If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CRF 1.801-1.809 and MPEP 2402-2411.05, applicants may provide assurance of compliance by statement, affidavit or declaration or by someone empowered to make the same or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 2 is directed to an immunosuppressant comprising the claimed monoclonal antibody. Although the specification demonstrates how the claimed antibody can cause cytolysis of activated human lymphocytes, there is no evidence, data, or guidance showing that the antibody is capable of causing immunosuppression in a subject.

Accordingly, it would require undue experimentation for one skilled in the art to practice the claimed invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a remedy to treat HIV, does not reasonably provide enablement for a remedy for preventing. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 3 is directed to a remedy for HIV infection. The term "remedy" in the context of claim 3 encompasses treatments comprising the antibody of claim 1 and passive vaccines comprising the monoclonal antibody of claim 1. The term "vaccine," by definition, implies a preparation intended for active immunological prophylaxis.

Prophylaxis is defined as the prevention of disease or of a process that can lead to disease.

It is well known in the art and even to the general public that medical science, despite decades of intense research, has not found any antigen, immunogen, antibody or compound that can be credibly used as a vaccine against HIV.

The difficulties inherent to developing an HIV vaccine are well known. For the sake, of clarity, some of those problems are outlined here:

1) the extensive genomic diversity associated with HIV, due in large part to error prone reverse transcription of its RNA genome,

2) the fact that the modes of viral transmission include virus-infected mononuclear cells, which pass the infecting virus to other cells in a covert form (cell to cell transmission), as well as via free virus transmission,

3) the existence of latent forms of the virus,

4) the complexity and variation of the elaboration of the disease, and

5) the property of some portions of HIV proteins or peptides to actually cause immunosuppression or other detrimental consequences.

The existence of these obstacles prevents one of ordinary skill in the art from accepting any therapeutic regimen on its face given the intense interest in developing HIV treatments or vaccines and the lack of success in doing so.

The state-of-the-art vis-a-vis HIV vaccine development is one of unpredictability (Haynes et al., 1996; Burton and Moore, 1998; Moore and Burton, 1999; Desrosiers, R., 2004). To date, there is not one single effective HIV vaccine on the market.

Accordingly, when all the aforementioned factors are considered *in toto*, it would require undue experimentation for one skilled in the art to practice the claimed invention.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Nicole Kinsey White/
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648